K002094

Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

OCT - 6 2000

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Interventional Products Division C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	978 - 262 - 4867
Fax:	978 - 262 - 4878
Contact Person:	Marion Gordon, R.A.C.
Date of Preparation:	July 10, 2000

B. Device Name

Trade Name:	Bard® memotherm® Covered Esophageal Stent
Common/Usual Name:	Esophageal Stent
Classification Name:	Prosthesis, esophageal

C. Predicate Device Name

Trade Name:

1. Ultraflex™, Boston Scientific Corporation
2. Bard® memotherm-FLEXX™ Biliary Stent
   C.R. Bard, Inc., Peripheral Technologies Division
3. IMPRA ePTFE Arteriovenous Cuffed Graft
   IMPRA, a Subsidiary of C.R. Bard, Inc.

D. Device Description:

The Bard® memotherm® Covered Esophageal Stent is a covered self-expanding nitinol stent, which is pre-mounted on a deployment system manufactured with various materials commonly used in the medical device industry. The compressed stent is mounted between the outer transparent sheath and the inner carrier catheter. Pulling the draw button on the proximal end of the handgrip activates the stent release mechanism. The safety seal and a splitting wire, which is connected to the draw button and guided in a loop over the wall of the outer

sheath, will split the outer sheath over the length of the stent section. The stent is then free to expand and assume its final configuration.

E. Intended Use:
The Bard® memotherm® Covered Esophageal Stents is indicated for palliative treatment in maintaining luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of a concurrent esophageal fistula.

F. Technological Characteristics Summary:
The Bard® memotherm® Covered Esophageal Stent is a metal stent constructed of biocompatible nitinol. The self-expanding stent is packaged pre-mounted on a disposable delivery system that utilizes a 'zipper' release mechanism.

The Bard® memotherm® Covered Esophageal Stent is substantially equivalent to the Ultraflex™ manufactured by Boston Scientific. Both devices are manufactured with a delivery system that implants a self-expanding metal stent over a guidewire using a coaxial, interfacing catheter/sheath (tubes). While each manufacturer's metal stent are made from different formulations of nitinol, both allow for self-expanding deployment using radial force to expand in the esophagus. Both manufacturers provide covered stents using materials that are well characterized and known in the medical device industry. Both the Ultraflex™ and memotherm® have the same intended use and target patient populations and are available within the same range of diameters and lengths. The stent technology and covering materials are currently used by other divisions of C.R. Bard, Inc.

G. Performance Data
Safe and effective *in vivo* use of self-expanding, metal stents in the esophagus has been demonstrated in relevant published, scientific, literature. Metal stents have been shown to be effective, in palliative treatment of esophageal cancers and concomitant fistulas, and give the patients relief from partial or complete obstructions caused by the disease.

Comparative performance testing was done, where appropriate, between the memotherm® and Ultraflex™. In addition to testing various tensile and dimensional verifications, other bench data included trackability, deployment and stent expansion/compression were completed. The stent is resistant to corrosion within the intended anatomical environment based on our testing and Bard's experience with other SEMS. All data, including biocompatibility, was within the anticipated results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Marion Gordon, R.A.C.
Senior Regulatory Affairs Coordinator
C.R. Bard, Inc.
Bard Interventional Products Division
129 Concord Road, Bldg. 3
Billerica, Massachusetts 01821

Re: K002094
Trade Name: Bard Memotherm Covered Esophageal Stent
Regulatory Class: II
Product Code: ESW
Dated: July 10, 2000
Received: July 11, 2000

Dear Ms. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002094

510(k) Number (if known): TBD

Device Name: Bard® memotherm® Covered Esophageal Stent

Indications For Use: The Bard® memotherm® Covered Esophageal Stent is indicated for palliative treatment in maintaining luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of a concurrent esophageal fistula.

Mark N Melkerson

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510(k) Number K002094

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)